

1 NOAH T. KATZEN
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11 UNITED STATES DISTRICT COURT
12 FOR THE EASTERN DISTRICT OF WASHINGTON
13

14 STATE OF WASHINGTON, *et al.*,

No. 1:23-cv-03026

15 Plaintiffs,

16 v.

DECLARATION OF NOAH T.
KATZEN

17 U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

18 Defendants.
19

20 Pursuant to 28 U.S.C. § 1746, I, Noah T. Katzen, hereby declare:

21 1. I am an attorney in the U.S. Department of Justice, Civil Division,
22 Consumer Protection Branch. I am assigned to represent Defendants in the above-
23 captioned case. The statements made herein are based on my personal knowledge,
24 and on information made available to me in the course of my duties and
25 responsibilities as Government counsel in this case.
26

2. I submit this declaration in support of Defendants' Response in Opposition to Plaintiff States' Motion for Preliminary Injunction.

3. Filed herewith as Exhibits A-K are true and correct copies of the following documents that have been provided to me by the U.S. Food and Drug Administration or that I downloaded from the indicated websites:

Exhibit No.	Exhibit Name
A	Supplement Approval for NDA 020687/S-014 (June 8, 2011), https://perma.cc/JJJ9-NYKQ (last visited March 17, 2023)
B	Supplement Approval for NDA 020687/S-022 (Apr. 11, 2019), https://perma.cc/WU6K-GFLF (last visited March 17, 2023)
C	REMS Modification Rationale Review (Dec. 16, 2021), https://perma.cc/P38G-3NU5 (beginning at page 41 of the PDF) (last visited March 17, 2023)
D	P. Cavazzoni to D. Harrison, et al. (Dec. 16, 2021), at https://www.regulations.gov/document/FDA-2019-P-1534-0016 (last visited March 17, 2023)
E	REMS Modification Notification for NDA 020687 (Dec. 16, 2021)
F	REMS Modification Notification for ANDA 091178 (Dec. 16, 2021)
G	CDER, Summary Review (Application Number: 020687Orig1s025) (Jan. 3, 2023), https://perma.cc/P38G-3NU5 (beginning at page 1 of the PDF) (last visited March 17, 2023)
H	CDER, Risk Assessment and Risk Mitigation Review(s) (Application Number: 202107Orig1s000) (Jan. 27, 2012), https://perma.cc/DZ3M-MX93 (last visited March 17, 2023)
I	Brief for the States of NY, et al., Alliance for Hippocratic Medicine, et al. v. FDA, et al., No. 2:22-cv-0223-Z, Dkt. 59-1 (N.D. Tex), available on ECF
J	A. Shah, M.D. to H. Balderas (May 19, 2020)
K	Supplemental Approval for NDA020687/S-025 (Jan. 3, 2023), https://perma.cc/5FTY-SY25 (last visited March 17, 2023)

1 I swear under penalty of perjury that the foregoing is true and correct.

2 Executed on March 17, 2023.

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5 /s/ Noah T. Katzen
6 NOAH T. KATZEN
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DECLARATION OF NOAH T. KATZEN